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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,970	12/13/2001	Marcus B. Gohlke	068349.0120	4120

7590 06/01/2004
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EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,970	GOHLKE, MARCUS B.	
	Examiner	Art Unit	
	Susan Coe	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 7, 2004 has been entered.
2. Claims 1, 3 and 5-18 are currently pending.
3. The declaration of Marcus B. Gohlke, filed May 7, 2004, has been considered.

Priority

As discussed in previous Office actions, applicant's have claimed domestic priority as a CIP of Application No. 09/778,294 which is a divisional of Application No. 09/370,654. These applications do not support a combination of beta-glucan and lactoferrin. Therefore, claims drawn to this composition are not granted a priority date based on these applications.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3, and 5-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/08960.

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The English translation of WO '960 is US Pat. No. 6,306,453. US '453 will be referred to for convenience.

US '453 teaches a composition that contains yeast glucan and lactoferrin (see claim 5). The glucan is specified as beta-glucan (see claim 7). The composition also contains numerous ingredients that are considered nutritionally acceptable carriers, diluents, and flavorings. The composition is in the form of a tablet (see column 3, lines 20-22). Each ingredient is present from 0.0001 to 10% by weight (see column 2, lines 24-27).

The reference does not specifically cite the source of the lactoferrin. However, lactoferrin is considered to be the same compound no matter the source of the lactoferrin.

5. Claims 1, 5, 6, 8, 9, and 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 6,241,983.

US '983 teaches a composition that contains beta-glucan and lactoferrin (see claims 1, 2, and 21). The composition is a powder and can contain numerous ingredients that are considered nutritionally acceptable carriers, diluents, and flavorings (see column 16, lines 11-17). The reference specifically discusses beta-glucan from oats (see column 9, lines 27-32). Mushroom and yeast beta-glucan are not discussed; however, beta-glucan is considered to be the same compound no matter the source. The reference discusses lactoferrin from bovine milk (see column 14, lines 18 and 19).

6. Claims 1, 3, and 5-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0119928.

US '928 teaches a composition that comprises lactoferrin and beta-glucan. The lactoferrin can be present from 0.909 to 6.67 percent by weight. The beta-glucan can be present

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from 0.001 to 10% by weight. The composition can also contain 5 to 83.3% colostrum (see claims 1, 3-5, and 9). Colostrum is considered to be a nutritionally acceptable flavoring. The composition is in chewable form, such as a lozenge or tablet (see paragraph [0069] and [0089]). The lactoferrin is from cattle (see paragraph [0063]). The beta-glucan can be from mushrooms, yeast, or oats (see paragraph [0023]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 7, 10, 11, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/08960.

As discussed above, WO '960 teaches a composition of lactoferrin and beta-glucan. The reference does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

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8. Claims 1, 3, 7, 10, 11, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,241,983 in view of US Pat. No. 5,670,138.

As discussed above, US '983 teaches a composition comprising lactoferrin and beta-glucan; however, the reference does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The reference also does not specifically teach formulating the composition in the forms claimed by applicant. These forms of administration are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on the knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the reference in the forms claimed by applicant.

In addition, the reference does not specifically teach combining beta-glucan and lactoferrin with lemon flavoring, mannitol, sorbitol, and silicon dioxide. However, US '138 teaches that these ingredients are used to formulate orally administered products (see column 6,

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lines 15 and 40-42). Therefore, an artisan of ordinary skill in the art would be motivated to use lemon flavoring, mannitol, sorbitol, and silicon dioxide in combination with the beta-glucan and lactoferrin to formulate an orally administered product.

9. Claims 1, 3, 7, 10, 11, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0119928 in view of US Pat. No. 5,670,138.

As discussed above, US '928 teaches a composition comprising lactoferrin and beta-glucan; however, the reference does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The reference also does not specifically teach formulating the composition in the forms claimed by applicant. These forms of administration are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on the knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the reference in the forms claimed by applicant.

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In addition, the reference does not specifically teach combining beta-glucan and lactoferrin with lemon flavoring, mannitol, sorbitol, and silicon dioxide. However, US '138 teaches that these ingredients are used to formulate orally administered products (see column 6, lines 15 and 40-42). Therefore, an artisan of ordinary skill in the art would be motivated to use lemon flavoring, mannitol, sorbitol, and silicon dioxide in combination with the beta-glucan and lactoferrin to formulate an orally administered product.

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, appearing to read "Susan D. Coe".

Susan D. Coe, Examiner
May 24, 2004